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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,667	01/13/2004	Hiroshi Maeda	Q79414	9625

23373 7590 12/14/2006

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EXAMINER	
WHITE, EVERETT NMN	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/755,667	MAEDA ET AL.	
	Examiner	Art Unit	
	Everett White	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed September 29, 2006 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

(A) Claims 2, 7-21 and 25-36 have been canceled;
(B) Claims 22-24 have been amended;
(C) Comments regarding Office Action have been provided drawn to:
  (I) 102(b) rejection, which has been withdrawn;
  (II) 103(a) rejection, which has been maintained for the reasons of record.

2. Claims 1, 3-6 and 22-24 are pending in the case.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3-6 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makuuchi et al (US Patent No. 6,117,815) in view of De Ambrosi et al (US Patent No. 4,987,222) for the reasons disclosed on pages 3-5 of the Office Action filed May 30, 2006.

5. Applicant's arguments filed September 29, 2006 have been fully considered but they are not persuasive. Applicants argue against the rejection on the ground that the Makuuchi et al patent does not recite irradiating an electron beam to a polysaccharide having a molecular weight range of 5,000 to 70,000 Da. This argument is not persuasive since the De Ambrosi et al patent shows irradiation of polysaccharides having molecular weights within this range is well known in the art. See, for example, Example 1, wherein heparin having a molecular weight of 14,000 Daltons is irradiated.

With respect to Claims 22-24, Applicants argue against the rejection by arguing that radiation with an electron beam can lower the molecular weight in a short time, whereas molecular weight lowered using gamma-ray radiation (see the De Ambrosi et al patent) requires longer times. This argument is not persuasive because no limitation of time as a description for the type of electron beam used to carry out the process has been disclosed in the instant claims. Gamma-ray radiation does emit electrons.

Applicants also argue against the rejection on the ground that the De Ambrosi et al patent does not disclose hyaluronic acid fraction having a molecular weight of 600 to 1200 kDa in a liquid state being irradiated with an electron beam ranging from 10 to 80 kGy to obtain a hyaluronic acid having a molecular weight ranging from 1300 to 4000 Da. This argument is not persuasive because the De Ambrosi et al patent does disclose gamma ray beam at doses within the range 2.5 to 20 Mrad (i.e., 25 to 100 kGy as pointed out by Applicants in their remarks) which covers part of the range of 10-80 kGy disclosed in instant Claims 22-24 and De Ambrosi et al discloses obtaining glucosaminoglycans (including hyaluronic acid) having a molecular weight between 1000 and 35,000 Daltons, which covers the molecular weight range of the hyaluronic acid of 1300 to 4000 Daltons disclosed in instant Claims 22-24. Even-though, the De

Ambrosi et al patent does not recite glucosaminoglycans having molecular weight of 600 to 1200 kDa, the instant claims having such molecular weights would still be rejected under 35 USC 103 since the instant specification discloses irridation of a hyaluronic acid which has an average molecular weight of 5,000 to 3,000,000 Da (see spec. at page 5, last paragraph). The 600 to 1200 kDa in the specification is only a preferred limitation and the criticality of this molecular weight range has not been pointed out. Molar proportions or ranges of molecular weight cannot be the basis for patentability of subject matter encompassed by the prior art where there is nothing to indicate such proportion or range is critical. *In re Hoeschele* (CCPA 1969) 406 F2d 1403, 160 USPQ 809; *In re Cole* (CCPA 1964) 326 F2d 769, 140 USPQ 230. If criticality is asserted for proportions or ranges, the specification must not disclosed them as merely preferred. *Hays v. Reynolds, Comr. Pats.* (DCDC 1965) 242 FSupp 206, 145 USPQ 665; *In re Bourdon* (CCPA 1957) 240 F2d 358, 112 USPQ 323. Accordingly, the rejection of Claims 1, 3-6 and 22-24 under 35 U.S.C. 103(a) as being unpatentable over the Makuuchi et al patent in view of the De Ambrosi et al patent is maintained for the reasons of record.

Summary

6. All the pending claims are rejected.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-066127. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

E. White

E. White

12/8/06

Shaojia A. Jiang
Supervisory Primary Examiner
Technology Center 1600